

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Chiem V. Pham

Application No.: Continuation of 10/060,235

Group Art Unit: N/A

Filed: December 1, 2003

Examiner: Not Yet Assigned

For: ACID END GROUP POLY(D,L-LACTIDE-CO-  
GLYCOLIDE) COPOLYMERS WITH HIGH  
GLYCOLIDE CONTENT

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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08a/b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted

herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
  - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
  - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
  - ☐ c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No.

\_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i).

- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☒ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. 10/060,235, filed February 1, 2002, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☒ 8. Copies of the documents were cited by or submitted to the Office in Application Nos. 10/060,235, filed February 1, 2002 and 09/635,677, filed August 10, 2000, which

are relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

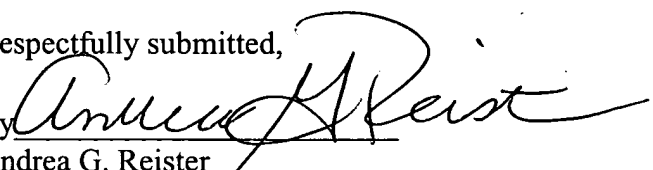
It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a/b, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0740, referencing Docket No. 00166.0106.US02.

Dated: December 1, 2003

Respectfully submitted,

By

  
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(202) 662-6000

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Chiem V. Pham
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	000166.0106-US02

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-4,157,437	06/1979	Okuzumi et al.	
	AB	US-4,677,191	06/1987	Tanaka	
	AC	US-4,719,246	01/1988	Murdoch et al.	
	AD	US-4,728,721	03/1988	Yamamoto et al.	
	AE	US-4,767,628	08/1988	Hutchinson	
	AF	US-4,797,468	01/1989	De Vries	
	AG	US-4,849,228	07/1989	Yamamoto et al.	
	AH	US-4,859,763	08/1989	Takayanagi et al.	
	AI	US-5,134,122	07/1992	Orsolini	
	AJ	US-5,192,741	03/1993	Orsolini et al.	
	AK	US-5,252,701	10/1993	Jarrett et al.	
	AL	US-5,320,624	06/1994	Kaplan et al.	
	AM	US-5,478,921	12/1995	Roby et al.	
	AN	US-5,641,501	06/1997	Cooper et al.	
	AO	US-5,650,173-B1	07/1997	Ramstack et al.	
	AP	US-5,654,008	08/1997	Herbert et al.	
	AQ	US-5,705,197	01/1998	Van Hamont et al.	
	AR	US-5,770,231-B1	06/1998	Mesens et al.	
	AS	US-5,792,477-B1	08/1998	Mesens et al.	
	AT	US-5,817,343	10/1998	Burke, Paul A.	
	AU	US-5,876,761	03/1999	Bodmer et al.	
	AV	US-5,916,598	06/1999	Rickey et al.	
	AW	US-5,942,253	08/1999	Gombotz et al.	
	AX	US-5,945,128	08/1999	Deghenghi	
	AY	US-5,952,405	09/1999	Schoenberg et al.	
	AZ	US-5,965,168-B1	10/1999	Mesens et al.	
	AA1	US-5,968,543	10/1999	Heller et al.	
	AB1	US-6,004,573	12/1999	Rathi, et al.	
	AC1	US-6,007,565	12/1999	Roby et al.	
	AD1	US-6,362,308	03/2002	Pham, Chiem V.	
	AE1	US-6,599,519	07/2003	Seo et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	DE-DE 28 27 289 A	01-11-1979	ETHICON		
	BB	EP-0 275 581-B1	08-12-1992	AKZO N.V.		
	BC	DE-DE 43 20 396 A	12-22-1994	Boehringer Ingelheim		
	BD	EP-0 299 730-B1	10-11-1995	Mitsui Toatsu Chemicals, Inc.		
	BE	EP-EP 0 816 413 A	01-07-1998	Novartis		

Examiner Signature		Date Considered	
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Chiem V. Pham
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	000166.0106-US02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	Bendix, "Analytical Studies on the Solubility Problem of Poly(D,L-Lactide-Co-Glycolide), 50:50," Proceed. Intern. Symp. Control. Rel. Bioact. Mater. 17: 248-49 (1990).		
	CB	Gilding et al., "Biodegradable polymers for use in surgery-polyglycolic/poly(lactic acid) homo- and copolymers: 1," Polymer 20:1459-1464 (1979).		
	CC	International Journal of Pharmaceutics, Vol. 141, 1996, pages 205-216, XP000946093; relevant passages: page 206, column 2, line 34 - page 207, column 1, line 34.		
	CD	Kulkarni et al., "Biodegradable Poly(lactic acid) Polymers," J. Biomed. Mater. Res., 5:169-81 (1971).		
	CE	Lewis, D.H., "Biodegradable Polymers as Drug Delivery Systems," (Chasin et al., eds.) (Marcel Dekker, Inc., NY), Chapter 1, 1-41 (1990).		
	CF	March, Jerry, "Advanced Organic Chemistry: Reactions, Mechanisms, and Structure," Second Edition (International Student Edition), McGraw-Hill Kogakusha, Ltd., C-720-C-726.		
	CG	Park, Tae Gwan, Degradation of poly(lactic-co-glycolic acid) microspheres: effect of copolymer composition," Biomaterials, 16: 1123-30 (1995).		
	CH	Resomer, Boehringer Ingelheim, pages 2-11 (02/94).		
	CI	Resomer RG 502 H, Boehringer Ingelheim Pharma GmbH & Co. KG at <a href="http://www.boehringer-ingelheim.com/finechem">http://www.boehringer-ingelheim.com/finechem</a> .		
	CJ	Wang et al., "Synthesis, characterization, biodegradation, and drug delivery application of biodegradable lactic/glycolic acid oligomes: I. Synthesis and characterization," J. Biomater. Sci. Polymer Edn. 8(12): 905-17 (1997).		
	CK	Wang et al., "Synthesis, characterization, biodegradation, and drug delivery application of biodegradable lactic/glycolic acid oligomes: Part II. Biodegradation and drug delivery application," J. Biomater. Sci. Polymer Edn. 9(1): 75-87 (1997).		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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